

Application No.: 09/744,622

Docket No.: HO-P01615US1

**AMENDMENTS TO THE DRAWINGS**

The attached sheet(s) of drawings the omitted drawing Figure 17a. Applicants assert that the submission of this drawing is not new matter as this drawing was contained in the provisional application as originally filed.

Attachment: Replacement sheet

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REMARKS

Claims 1-5, 6-14 and 55-63 are pending. Claims 6 and 15-54 have been canceled without prejudice and without acquiescence. Claims 1 and 5 have been amended without prejudice and without acquiescence to clarify the scope of the invention. Amendments for claim 1 can be found throughout the specification, more specifically, on pages 13, lines 10-30, page 14, lines 1-14, and page 16, lines 11-20. Claims 55-63 have been added. Support for these claims can be found throughout the entire specification, more specifically, page 14, lines 31-page 15, lines 4, and pages 38-67. Applicants retain the right to file a continuation and/or divisional application on any canceled subject matter. Applicants assert that no new matter has been added.

The issues outstanding in this application are as follows:

- Claim objection
- Specification objections
- Claims 5-12 and 54 are rejected under 35 U.S.C. 112, first paragraph as the specification does not enable any person skilled in the art to practice the invention.
- Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph as being indefinite.
- Claims 1-14 and 54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rubin (US 4,481,195).

Applicant respectfully traverses the outstanding objections and rejections, and applicant respectfully requests reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

#### I. Objections

##### A. Claim 54

The Examiner has objected to claim 54 under 37 C.F.R. 1.75 (c) as being of improper dependent form for failing to limit the subject matter of claim 1. Applicants traverse.

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However, in order to advance the prosecution of the present invention, Applicants cancel claim 54 without prejudice and without acquiescence.

#### B. Specification

The Examiner rejected the specification as containing minor informalities. The specification has been corrected as requested by the Examiner. Applicants assert that no new matter has been added.

#### II. 35 U.S.C. 112

##### A. First paragraph

Claims 5-14 and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for the treatment of Non-Hodgkin's lymphoma, prostate, carcinoma, glioblastoma multiforme or Kaposi's sarcoma, infections that result from *Borrelia burgdorferi*, *Mycobacterium leprae*, *Treponema pallidum*, HIV, hepatitis C, herpes virus or papillomavirus or infestations that result from *Candida*, *Sporothrix schenckii*, *Histoplasma*, *paracoccidioides*, *Aspergillus*, *Leishmania*, malaria, *acanthamoeba* or cestodes does not reasonably provide enablement for the treatment of malignancies, i.e., cancer in general, infections in general, infestations in general or all other medical conditions. Applicants traverse.

Applicants remind the Examiner that the general standard for enablement under §112, first paragraph has been addressed in the case law repeatedly. For example, in *In re Wright*, 999 F.2d 1557, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993), the court stated that an enabling Specification teaches those skilled in the art how to make and use the claimed invention in its full scope without "undue experimentation." *In re Wright*, 999 F.2d at 1560. It is well-settled patent law that the first paragraph of § 112 requires nothing more than objective enablement. *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). This objective enablement may be provided through broad terminology or illustrative examples. *Id.* The PTO bears the initial burden, in rejecting a claim under the enablement requirement of §112, to set forth "a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the

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invention provided in the Specification of the application." *In re Wright*, 999 F.2d at 1561-62 (citing *Marzocchi*, 439 F.2d at 223-24, 169 U.S.P.Q. at 369-70).

The Cecil reference that the Examiner relies upon to indicate that there is no "one" agent to treat all cancers is not relevant. This 2000 textbook reference is merely providing an overview for cancer treatment. On pages 1060, the reference emphasizes diagnosis and overall assessment as keys for cancer treatment. The Examiner further indicates that the Cecil reference also indicates that there is no "one" agent to treat infestations or infections. Applicants assert that this reference is merely providing a summary of the known therapies known to treat infestations or infections. The reference does not indicate that there is unpredictability in the art to utilize an agent to treat multiple types of infestations or infections and/or cancer. In fact, if anything, this reference illustrates that those of skill in the art are capable of understanding the complexities of these conditions and based upon the description in the specification would be able to assess if the agent of the present invention is capable of treating the condition.

Even if the claims encompass inoperative embodiments, such as where the agent does not treat or diagnosis a condition, this is not prohibited by the statutes. The Federal Circuit has explained that the fact that claims may encompass inoperative embodiments does not necessarily render them non-enabled, or invalid. *See Atlas Powder Co. v. E. I. duPont de Nemours & Co.*, 224 U.S.P.Q. 409, 414 (Fed. Cir. 1984).

It is not the function of the claims to exclude possible inoperative substances. *Atlas Powder*, 224 U.S.P.Q. at 414. Section 112 simply requires that there be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill in the relevant art how to make and use the invention as broadly as it is claimed (emphasis added). *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Satisfaction of the enablement requirement is not precluded by the necessity of some experimentation. *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). *In Angstadt*, the predecessor court to the Federal Circuit found that disclosure of many operable embodiments and one inoperative embodiment did not render a claim broader than the enabled scope because determination of the operable embodiments did not involve undue experimentation. *In re Angstadt*, 537 F.2d 498, 502-503, 190 USPQ 214, 218 (CCPA 1976).

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As has been determined by the courts, the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Even if experiments are necessary, a considerable amount of routine experimentation is permissible, especially where the Applicants' specification provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed. *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Applicants assert that the abundance of examples provide one of skill in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

In fact, time-consuming experiments are acceptable if the type of experimentation is standard in the art. An extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance. *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). Yet further, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Wands*, 858 F.2d 737, 8 USPQ2d 1404 (Fed. Cir. 1985); *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd sub nom. Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)).

Determination of whether a rejection is appropriate based on the scope of a claim relative to the scope of the enablement depends on two factors: 1) how broad the claim is with respect to the disclosure; and 2) if one skilled in the art is enabled to make and use the entire scope of the invention without undue experimentation. M.P.E.P. §§ 2164.08. Applicants assert that the claims are not too broad, given the amply disclosure and guidance therein, and that undue experimentation is not required by the skilled artisan to make and use the invention. In view of these comments, Applicants respectfully request that the rejection be withdrawn.

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**B. Second paragraph**

Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants traverse.

The Examiner indicates that the terms "analog" and "derivative" are indefinite. In the specification on pages 63-67, Applicants describe how to synthesize novel derivatives and analogs. Thus, Applicants assert that one of skill in the art would be able to determine the scope of the claims, when the claims are read in light of the specification. See *North Am. Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993). Thus, Applicants request that this rejection be withdrawn.

**III. 35 U.S.C. 102**

Claims 1-14 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubin (US Patent No. 4,481,195). Applicants traverse.

In order to advance the prosecution of the present invention, Applicants have amended without prejudice and without acquiescence independent claim 1 to indicate that the present invention is directed to whole body hyperthermia. As the Examiner indicated in the pending Office Action on page 13, "Rubin expressly disclosed that local hyperthermia in the region of the suspected tumor cells..." Applicants assert that local hyperthermia is not similar to whole body hyperthermia, thus Rubin does not mention all the limitations of independent claim 1. Likewise, dependent claims 2-5, and 6-14 by definition incorporate all the limitations of independent claim 1. Thus, Rubin does not anticipate independent claim 1 and its dependent claims. In view of the above, Applicants request that the rejection be withdrawn.

**CONCLUSION**

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P01615US1 from which the undersigned is authorized to draw.

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Respectfully submitted,

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Attachments

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 Inventor: Nicholas Bachynsky et al.  
 Title: CHEMICALLY INDUCED INTRACELLULAR  
 HYPERTHERMIA  
 REPLACEMENT SHEET

FIG. 17(a)	TREATMENT	PLASMA RNA LEVEL (copies/ml)*	CDA+T CELLS (cells/mm <sup>3</sup> )**	KAPOSI'S LESION (size;% regression)
	Day 5	400,000	250	1x2 cm/0%
		50,000	200	0.6x1.3 cm/60%
			280	0/100%
	Week 4	non-detected	390	0/100%
	Week 6	non-detected	420	0/100%
	Week 12	non-detected	400	0/100%
	Week 16	non-detected		
				*Amplicor™ (Roche)
				**Flow Cytometry

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